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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Marian L. Kruzel

Serial No: 10/023,096

Filed: 12/18/2001

Title: Treating Compositions with
Lactoferrin

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Art Unit 1649

Examiner:
Gucker, Stephen.

Attorney Docket
FDI004

APPEAL BRIEF

Mail Stop Appeal Brief - Patents

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Sir:

Applicant hereby files this Brief and encloses a check for \$ 250 to pay for
the fee.

A notice of appeal was filed on 02/09/2006 in this Application.

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TABLE OF CONTENTS

I.	REAL PARTY IN INTEREST	3
II.	RELATED APPEALS AND INTERFERENCES.....	3
III.	STATUS OF THE CLAIMS.....	3
IV.	STATUS OF THE AMENDMENTS.....	3
V.	SUMMARY OF THE CLAIMED SUBJECT MATTER.....	3
VI.	GROUND OF REJECTION TO BE REVIEWED ON APPEAL.....	5
VII.	ARGUMENT.....	6
VIII.	CLAIMS APPENDIX.....	14
IX.	EVIDENCE APPENDIX.....	15
X.	RELATED PROCEEDINGS APPENDIX.....	15

Real Party in Interest

The real party in Interest is the inventor, Marian L. Kruzel.

Related Appeals and Interferences

Applicants are unaware of any related appeals or interferences.

Status of Claims

Originally filed claims: 1- 12

Claims cancelled: 8-12

Presently pending claims 1-7

Presently appealed claims: 1-7

Status of Amendments

There are no outstanding amendments.

Summary of the Claimed Subject Matter

It is necessary to give a brief history of the application to summarize the Claimed Subject Matter of this application.

This application was filed on **12/18/2001** with a **Preliminary Amendment to Declare an Interference with U.S. 6,172,040.**

Claim 1 as filed herein recited:

1. A method for reducing the microbial contamination of a meat product, comprising treating the meat product with a sufficient amount of lactoferrin to reduce microbial contamination.;

and this claim was identical with claim 1 in U.S. Serial No. 09/322,700 upon which

U. S. 6,172,040 is based.

In an Office Communication mailed 06/15/2004, Applicant was notified that : **"All claims are allowed"**. Further, "due to a potential interference prosecution is SUSPENDED FOR A PERIOD OF SIX MONTHS from the date of this letter."

The Examiner in this application then called the undersigned and stated that the allowance of the claims was being withdrawn. and no interference would be declared. This was confirmed by the undersigned in a fax dated 2/16/2005 and a Office Action mailed 2/17/2005.

The Examiner withdrew the allowance of claims and made a first rejection of claims in an Office Action mailed 6/09/2005.

A final rejection of the claims was mailed 1/31/2006, now four years after filing the application.

The summary of claimed subject matter is defined by independent claims 1 and 3 which recite:

1. A **method** for reducing the microbial contamination of a meat product, comprising **treating** the meat product with a sufficient amount of lactoferrin selected from the group consisting of bovine, human, and recombinant human lactoferrin to reduce microbial contamination.
3. A method for reducing the microbial contamination of a meat product, comprising **treating the meat product with** a sufficient amount of lactoferrin selected from the group consisting of bovine, human, and recombinant human

lactoferrin mixed with a carrier to reduce microbial contamination.

Grounds of rejection to be Reviewed on Appeal

I. The refusal of the Examiner to institute an interference;

II. The rejection of Claims 1-7 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement; and

III. The Examiner fails to establish a *prima facie* case of obviousness in the following rejections.

Claims 1-7 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Chander et al. ("Chander") in view of Dickson et al. ("Dickson") for reasons of record.

Claims 1-7 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Chander et al. ("Chander") in view of Stiles et al. ("Stiles") for reasons of record.

Claims 1-7 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Chander et al. ("Chander") in view of Ryser et al. ("Ryser") for reasons of record.

Arguments

I. Failure to institute interference with US 6,172,040

Claim 1 of the patent reads:

"A method for reducing the microbial contamination of a meat product, comprising treating the meat product with a sufficient amount of lactoferrin *immobilized on a naturally occurring substrate via the N-terminal region of the lactoferrin* to reduce microbial contamination.

The basis for the term "*immobilized on a naturally occurring substrate via the N-terminal region of the lactoferrin*" found in the patent and claims is mixing the lactoferrin with the substrate. It is therefore inherent and not a modification of the lactoferrin.

Claim 3 of this application reads:

A method for reducing the microbial contamination of a meat product, comprising treating the meat product with a sufficient amount of lactoferrin *selected from the group consisting of bovine, human, and recombinant human lactoferrin* mixed with a carrier to reduce microbial contamination.

The two claims differ in that the patent uses the term "**substrate**" whereas this application uses the term "**carrier**". However, the terms as illustrated in the respective disclosures include identical materials (see analysis in Applicant's Preliminary Amendment filed with the present application). It is clear that the Examiner from the history of the prosecution (see Office communication mailed 06/15/2004) recognized that claims of the present application were allowable and were directed to the same invention as claimed in the patent; and accordingly

there was a potential interference that required suspension rather than issuing a Notice of Allowance and Fee(s) Due that would have resulted in a new Patent. There is no question that an interference was required and the next procedural step since the sole question was now priority.

However, the Examiner almost one year later made a rejection of Applicant's claims. This attack on the invention that was in the patent is procedurally unwarranted, the Examiner was without authority to attack the patent claim since 35 U.S.C. §282 states: "A patent shall be presumed valid." The error in procedure is for the Examiner to deny Applicants ability to initiate an interference of common subject matter with an existing patent.

It is respectfully submitted that, priority is the relevant issue in an interference. It is the sole responsibility of the Board of Patent Appeal and Interference to determine who among parties claiming the same invention are to be given a patent and issue the determination to a patent holder that patent claims are not valid.

It is respectfully submitted that it is procedurally unwarranted and lacks procedural integrity to have the Board make a determination only on patentability of Applicant's claims and either 1) sustain the Examiner's rejection and ignore the statutory requirement of 35 U.S.C. §282, thus making an inconsistent and nonbinding determination on the validity of the patent claims in US 6,172,040 or 2) reverse the Examiner's rejection and being in a quandary whether to follow the normal practice of allowing the Examiner to send a Notice of Allowance and Fee(s) Due when the Examiner has been reversed or remanding to the

Examiner for the purposes of setting up an interference.

It is Applicant's position that the Examiner lacks authority after making the determination that an Applicant has claimed the same invention as a claim(s) in a Patent to take any other action than to declare an interference for the Board of Patent Appeal and Interference to make a determination of priority.

II. The rejection of Claims 1-7 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

In a Office Communication of 02/22/2006 in response to a telephone interview, the Examiner states:

"Applicant correctly indicated to the Examiner that the new matter rejection made in the last Office Action (1/31/06) was in error as Applicant found support for his amendment on page 14 of the specification, and the Examiner agreed and apologized to Applicant, " The apology is accepted and the formal withdrawal of this rejection is requested.

III. The Examiner fails to establish a *prima facie* case of obviousness.

The Examiner fails to establish that the combination of references shows the invention recited in Claim1-7.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. **MPEP §2143**

Chander et al. article

In each of the three rejections of Claims 1-7 over art, the Chander et al. article “Lactoferrin – Antibacterial Protein of Milk” is the primary or first reference. Each of Claims 1-7 begin:

“A method for reducing the microbial contamination of a meat product, comprising treating the meat product...”

The Chander article makes **no reference** to **treating any** product. This is a technical article about lactoferrin with a significant statement: “The role of iron is most important in the bacteriostatic activity of lactoferrin.” The conclusion of the article is: “..it is now evident that lactoferrin plays an important role in milk in controlling food poisoning, pathogenic and spoilage organisms of considerable importance.” This role is not a part of **treating** milk but because of the natural existence of lactoferrin in milk. It is respectfully submitted that the article fails to disclose, suggest or motivate the treating of **any** product (meat is not even mentioned).

In each of the three rejections of Claims 1-7 over art, a separate article, namely, Dickson et al., Stiles et al., and Ryser et al. is proposed as a secondary reference to be combined with the Chander et al. article.

Dickson et al. article – “Cell Surface Charge Characteristics and Their Relationship to Bacterial Attachment to Meat Surfaces”

The Dickson et al. article states: “The object of this study has as its objective the relationship between cell surface charge and bacterial attachment to meat surfaces.” Contrary to the Examiner’s statement that certain bacteria

“do contaminate meat surfaces”, upon examination of the article at most it can be said that by the **Attachment experiments** that certain bacteria that were mixed with aseptic strips of lean beef muscle or fat tissue resulted in the attachment of the bacteria. That disclosure is not a disclosure that these bacteria are normal contaminants of meat. There is **nothing** in this article that involves the **treating of the meat** to reduce microbial contamination of any bacteria.

It is respectfully submitted that since the Chander et al. article and the Dickson et al. article fail to disclose **treating of the meat**, the proposed combination of these two references is an erroneous piecemeal reconstruction of the cited articles that fail to establish a *prima facie* case of obviousness and the rejection of claim 1-7 is respectfully in error. As stated in *In re Oetiker*, 977 F. 2d 1443, 1447 (Fed. Cir. 1992): “There must be some reason, suggestion, or motivation found in the prior art whereby a person of ordinary skill in the field of the invention would make the combination. That knowledge can not come from the applicant’s invention itself.”

Stiles et al. – *Enterobacteriaceae* Associated with Meats and Meat Handling

The Stiles et al. article states on page 867, column 2: “The significance of these organisms in retail meats could not be determined. Hence, our objective was to study *Enterobacteriaceae* at different stages of the meat-processing chain to determine whether any associations could be made between bacteria isolates and stage in the meat handling process.” There is **nothing** in this article that involves the **treating of the meat** to reduce microbial contamination.

It is respectfully submitted that since the Chander article and the Dickson article fail to disclose **treating of the meat** that the proposed combination of

these two references is an erroneous reconstruction of the cited articles that fail to establish a *prima facie* case of obviousness and the rejection of claim 1-7 under 35 U.S.C. § 103 (a) as being unpatentable over Chander in view of Stiles et al. is respectfully in error.

Furthermore, the treatment of the meat to reduce microbial contamination would destroy the stated purpose of the Stiles et al. article. See the stated purpose of Stiles et al. above. If the meat was **treated to destroy microbial contamination at any stage in the meat processing chain** then Stiles would have found no evidence of bacteria at various stages or on equipment. References are not properly combinable or modifiable if their intended function is destroyed:

If a prior art reference is cited that requires some modification in order to meet the claimed invention or requires some modification in order to be properly combined with another reference and such modification destroys the purpose or function of the invention disclosed in the reference, one of ordinary skill in the art would not have found a reason to make the claimed modification. See *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984).

Ryser et al. – “New” food- borne pathogens of public health significance

The Ryser et al. article is a survey of recent work by epidemiologists and microbiologists that uncovered several hitherto unrecognized food-borne pathogens of public health significance. However, there is **nothing** in this article that involves the **treating of products and especially meat** to reduce microbial contamination.

It is respectfully submitted that since the Chander et al. article and the Ryser et al. article fail to disclose **treating of the meat**, accordingly the proposed combination of these two references is completely unwarranted.

The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

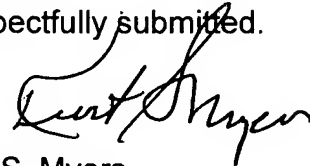
It is respectfully submitted that the holding above is applicable to all three rejections over art since **the reasonable expectation of success** is not found in the prior art. The Examiner in all three rejections having failed to find any reasonable support in the art cited, attempts to make an unwarranted and unfounded conclusion based on "The economic and public health desire..." where the Examiner arrives at the conclusion that the claims are *prima facie* obvious. This statement is clearly in error since it is made without any evidence, any reference or patent to support the conclusion and is a naked subjective assertion. For this reason the rejection made on this conclusion is in error and the rejection should be withdrawn.

The Examiner has failed to establish a *prima facie* case of obviousness. 35 USC § 102 states: "**A person shall be entitled to a patent unless** – ", accordingly, the burden is on the Examiner to establish that the applicant is not entitled under the law to a patent. This burden has not been met. Claims 1-7 should be allowed and such action is respectfully requested.

For the reasons stated above, applicant respectfully submits that the rejections of claims 1-7 should be reversed. Claims 1-7 should be allowed and such action is respectfully requested.

A check for \$250 is enclosed for the fee.

Respectfully submitted.



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CERTIFICATE OF MAILING

I hereby certify that this Appeal Brief is being deposited with the U.S. Postal Service as Express Mail (EQ 706308964 US) in an envelope addressed to: Mail Stop Appeal Brief – Patents, Commissioner for Patents, P.O. Box 1450, Alexandria, VA. 22313-1450 on May 4, 2006


Kurt S. Myers

Claims Appendix

1. A method for reducing the microbial contamination of a meat product, comprising treating the meat product with a sufficient amount of lactoferrin selected from the group consisting of bovine, human, and recombinant human lactoferrin to reduce microbial contamination.
2. A method for reducing the microbial contamination of a meat product, comprising treating the meat product with a sufficient amount of isolated lactoferrin selected from the group consisting of bovine, human, and recombinant human lactoferrin to reduce microbial contamination.
3. A method for reducing the microbial contamination of a meat product, comprising treating the meat product with a sufficient amount of lactoferrin selected from the group consisting of bovine, human, and recombinant human lactoferrin mixed with a carrier to reduce microbial contamination.
4. A method for reducing the microbial contamination of a meat product, comprising treating the meat product with a sufficient amount of lactoferrin selected from the group consisting of bovine, human, and recombinant human lactoferrin mixed with a nutritionally acceptable carrier to reduce microbial contamination.
5. A method for reducing the microbial contamination of a meat product, comprising treating the meat product with a sufficient amount of isolated lactoferrin selected from the group consisting of bovine,

human, and recombinant human lactoferrin mixed with a nutritionally acceptable carrier to reduce microbial contamination.

6. A method in accordance with claim 1, wherein said lactoferrin is a recombinantly produced lactoferrin.

7. A method in accordance with claim 3, wherein said lactoferrin is a recombinantly produced lactoferrin.

Evidence Appendix

None

Related Proceedings Appendix

None